The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DIETMAR HUGLIN, JOACHIM F. RODING, ANDREAS W. SUPERSAXO, and HANS G. WEDER

> Appeal No. 2004-1983 Application No. 10/016,903

MAILED

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ON BRIEF

Before WINTERS, SCHEINER, and ADAMS, <u>Administrative Patent Judges</u>. WINTERS, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 32, 33, and 35 through 43, which are all of the claims remaining in the application.

The Invention

The invention relates to a method for preparing a cosmetic formulation of a lipophilic cosmetically active agent in the form of an aqueous nanodispersion. The method consists essentially of (α) mixing specified amounts of a phospholipid, a

polyoxyethylene coemulsifier, a lipophilic cosmetically active agent, and ethanol with conventional stirring apparatus until a homogeneous clear liquid is obtained; and (β) adding the liquid obtained in step (α) to a water phase, wherein step (β) is carried out "in the absence of high shear or cavitation forces," and wherein the particles in the nanodispersion have an average diameter of $\langle 50 \text{ mn}.$

Claim 32, which is illustrative of the subject matter on appeal, reads as follows:

- 32. A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, which steps consist essentially of
- (α) mixing the components
- (a) 0.1 to 30 % by weight of a phospholipid,
- (b) 1 to 50 % by weight of a polyoxyethylene coemulsifier selected from the group consisting of polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, polyethoxylated fatty alcohols and salts thereof, polyethoxylated fatty amines and fatty acid amides and polyethoxylated carbohydrates,
- (c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic C_4 - C_{18} triglyceride and a lipophilic cosmetically active agent, in which any cosmetically active agent is lipophilic and is always present in component (c), and
- (d) 7.40 to 14.2 % by weight of ethanol,

with conventional stirring apparatus until a homogeneous clear liquid is obtained, and

 (β) adding the liquid obtained in step (α) to a water phase, wherein step (β) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter of $\langle 50 \text{ nm}.$

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The Prior Art

In rejecting applicants' claims under 35 U.S.C. § 103(a), the examiner relies on the following prior art reference:

Kakoki et al. (Kakoki)

(European Patent Application)

EPA 0 349 150 A2

Jan. 3, 1990

The Rejection

Claims 32, 33, and 35 through 43 stand rejected under 35 U.S.C. § 103(a) as unpatentable over European Patent Application 0 349 150. This rejection presents the only issue remaining for review. As stated in the Examiner's Answer mailed February 20, 2004, section (6), previously entered rejections under 35 U.S.C. § 112, second paragraph; 35 U.S.C. § 102; and 35 U.S.C. § 103 have been withdrawn.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief received October 24, 2003; (3) the Examiner's Answer mailed February 20, 2004; and (4) the above-cited prior art reference.

On consideration of the record, including the above-listed materials, we <u>affirm</u> the examiner's rejection under 35 U.S.C. § 103(a).

Discussion

In section (7) of their Appeal Brief, applicants refer to issue "D" which includes the rejection of claims 32, 33, and 35 through 43 under 35 U.S.C. § 103(a) as unpatentable over European Patent Application 0 349 150 and other rejections now withdrawn. According to applicants, "[c]omposition claims 37-43 are argued separately for issue D." Id.

However, in the argument section of their Appeal Brief, applicants do <u>not</u> present a separate argument for claims 37 and 38; in fact, those claims are not even mentioned in the relevant portion of the Appeal Brief. Respecting dependent claims 39 through 43, applicants merely state that "the cosmetic forms of claims 39-43 are unsuggested." Appeal Brief, section (8), page 6, fourth paragraph. That bald statement does not constitute an argument for claims 39 through 43 with a reasonable degree of specificity. Accordingly, for the purposes of this appeal, we shall treat dependent claims 33 and 35 through 43 as standing or falling together with claim 32. <u>See</u> 37 CFR § 1.192(c)(7) and (c)(8) (2003).

We find no error in the examiner's determination that the method sought to be patented in claim 32 would have been obvious at the time the invention was made to a person having ordinary skill in the art, based on the disclosure in European Patent Application 0 349 150.

Initially, we note that applicants do not predicate patentability on mixing step (α) recited in claim 32. Applicants do <u>not</u> argue that the cited reference fails to disclose mixing a phospholipid, a polyoxyethylene coemulsifier, a lipophilic cosmetically active

agent, and ethanol in relevant amounts meeting the terms of claim 32 "with conventional stirring apparatus until a homogeneous clear liquid is obtained." Nor do applicants argue that the recited particle size of their nanodispersion ("particles in the nanodispersion have an average diameter of (50 nm") serves to patentably distinguish over the cited prior art. Nor do applicants argue that any other characteristic or property of the cosmetic formulation prepared in claim 32 patentably distinguishes over the cited prior art.

According to applicants, "EP [European Patent Application 0 349 150] reverses the order of addition, i.e. the water is added to the non-aqueous phase. Claim 32 requires adding the non-aqueous phase to the water [in step (β)]." See the Appeal Brief received October 24, 2003, section (8), page 6, lines 1 and 2. Applicants do not contend, however, that merely reversing the order of addition, as reflected in claim 32, step (β) amounts to a non-obvious modification of the process disclosed by the cited European Patent Application. Applicants simply make the point, conceded by the examiner, that the method recited in claim 32 is not identically described in European Patent Application 0 349 150 within the meaning of 35 U.S.C. § 102. We agree with the examiner that it would have been within the skill of the art, and obvious to a person having ordinary skill, to reverse the order of addition described in European Patent Application 0 349 150; that is, to add the non-aqueous phase to water. Again, on this record, applicants do not rely on the order of addition specified in claim 32, step (β), as distinguishing over the prior art within the meaning of 35 U.S.C. § 103.

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In their Appeal Brief, page 6, fourth paragraph, applicants present the following argument:

Since the EP clearly teaches and exemplifies use of a homomixer, i.e. high shear mixing, in the step wherein the non-aqueous phase and the water are mixed, while process claim 32 requires the <u>absence</u> of high shear or cavitation forces, the EP clearly teaches away from the claimed invention. How can it be obvious, from a reference, to do the exact opposite of what it teaches?

That argument is predicated on a faulty interpretation of the prior art and, accordingly, lacks merit.

As stated in European Patent Application 0 349 150, page 4, lines 29 through

42:

The transparent composition of the present invention can be obtained by treating a mixed dispersion containing the above-mentioned essential components in an emulsifier, such as a homomixer conventionally used in the production of cosmetics. The transparency, safety, and stability of the transparent composition according to the present invention can be further improved when the mixture is treated in an emulsifier capable of providing a stronger shearing force than a conventional homomixer. Examples of such emulsifiers are the Manthon Gaulin, the French press, the colloid mill, the microfludizer, and the sonication emulsifying machine. This treatment [sic] be performed for either the whole amount of the system, or in some cases a part of the system, followed by dilution with other formulations such as water or polyhydric alcohol.

The 'strong shearing force treatment' used herein means the treatment in which an emulsifier capable of providing a stronger or higher shearing force than a mixer (e.g., a homomixer, Disper, a propeller type mixer) conventionally used in the production of cosmetics. Examples of such emulsifiers are a high pressure homogenizer (e.g., Manthon Gaulin, French press, Microfluidizer) preferably operating under a pressure of 500 psi or more, more preferably 2000 psi or more, a colloid mill preferably operating at 1000 rpm or more, more preferably 5000 rpm or more, or an ultrasonication emulsifier. (Emphasis added)

Applicants' argument to the contrary, notwithstanding, we find that European Patent Application 0 349 150 does not equate the use of a homomixer with high shear mixing. Rather, as seen from the above-quoted passages, the reference draws a contrast between "a homomixer, conventionally used in the production of cosmetics" and "an emulsifier capable of providing a stronger shearing force than a conventional homomixer." A "strong shearing force treatment," according to the reference, means treatment using an emulsifier capable of providing a stronger or higher shearing force than a conventional homomixer. For example, a "strong shearing force treatment" is provided by Manthon Gaulin high-pressure homogenizer.

Additionally, we invite attention to Examples 4-6 and Comparative Example 2 of European Application 0 349 150 where "preparations were prepared in the same manner as in Examples 1-3 and the Comparative Example, except that the Manthon Gaulin was replaced by a homomixer." (Id., page 5, lines 45 and 46, emphasis added). Table 2 of the reference, page 6, illustrates that Examples 4, 5, and 6 provide good safety, stability, and transparency, albeit stability and transparency can be further improved by use of pressure emulsification carried out by a Manthon Gaulin (Examples 1, 2, and 3). We think it clear that Examples 1 through 6 illustrate the invention of European Patent Application 0 349 150, in contrast with Comparative Examples 1 and 2.

Having carefully reviewed European Patent Application 0 349 150 in its entirety, we disagree that the cited reference teaches away from claim 32, step (β) "carried out in the absence of high shear or cavitation forces."

The examiner's decision rejecting claim 32 under 35 U.S.C. § 103(a) as unpatentable over European Patent Application 0 349 150 is <u>affirmed</u>. As previously indicated, claims 33 and 35 through 43 fall together with claim 32.

Other Issue

One further matter warrants attention.

Claim 37, which covers a cosmetic formulation in the form of a gel, reads as follows:

37. A cosmetic formulation in the form of a gel having incorporated therein a nanodispersion as defined in claim 32 comprising a lipophilic cosmetic active agent. (Emphasis added)

It can be seen that product claim 37 depends from method claim 32; and that claim 37 is couched in product-by-process language in view of the recitation "a nanodispersion as defined in claim 32." The nanodispersion recited in claim 37 is "defined in claim 32," i.e., prepared by the process set forth in claim 32.

As stated in <u>In re Thorpe</u>, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985),

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. (Citations omitted)

and

The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. (Citations omitted).

Following those principles applicable to product-by-process claims, we conclude that the nanodispersion recited in claim 37 "reads on" the nanodispersion prepared by steps (α) and (β) set forth in claim 32 or the same nanodispersion even if prepared by another sequence of steps. It would appear, therefore, that claim 37 is not limited by the specific sequence of method steps set forth in claim 32 and cannot properly "be construed to incorporate by reference all the limitations of the claim to which it refers [claim 32]." 35 U.S.C. § 112, fourth paragraph. Stated another way, it would appear that claim 37 could be literally infringed without carrying out steps (α) and (β) recited in claim 32.

Essentially the same commentary and reasoning applies to dependent claims 38 through 43.

Accordingly, on return of this application to the Examining Corps, we recommend that the examiner review claims 37 through 43 for compliance with 35 U.S.C. § 112, fourth paragraph, stating that

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers. (Emphasis added)

Conclusion

In conclusion, for the reasons set forth in the body of this opinion, we <u>affirm</u> the rejection of claims 32, 33, and 35 through 43 under 35 U.S.C. § 103(a) as unpatentable

over European Patent Application 0 349 150. Additionally, on return of this application to the Examining Corps, we recommend that the examiner review claims 37 through 43 for compliance with 35 U.S.C. § 112, fourth paragraph.

The examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

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APPEALS AND

) INTERFERENCES

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